

REMARKS

Applicants would like to respectfully point out that the inventors are incorrectly listed on the Filing Receipt for the present application as Ian Michael Whitehead, Alan John Slusarenko, Urs Wäspi, Duncan James Horatio Gaskins, Alan Ricard Brash and Nathalie Tijet. The inventors of the invention being claimed in this application, and as correctly set forth in the Continuation Application Transmittal Form filed on January 9, 2002, are Ian Michael Whitehead, Alan John Slusarenko, Duncan James Horatio Gaskins, Alan Ricard Brash and Nathalie Tijet. Therefore, Urs Wäspi should not be listed as an inventor. Applicants respectfully request that the correct inventorship for this application be noted.

Claims 1-21 are pending in this application. Although applicants believe that one of skill in the art would readily recognize that the term "fatty acid 13-hydroperoxide lyase" encompasses enzymatic activity, claims 1-3 and 16-18 are amended herein, as suggested by the Examiner, to recite that the recombinant protein has fatty acid 13-hydroperoxide lyase activity. Support for these amendments can be found in claims 1-3 and 16-18 as filed, on page 7, lines 18-21 of the specification and elsewhere throughout the specification. Claims 16-18 are also amended herein to more particularly define hybridization conditions. Support for these amendments can be found in claims 16-18 as originally filed, on page 9, line 27, through page 10, line 18, of the specification and elsewhere throughout the specification. No new matter is believed to be added by these amendments. Thus, applicants respectfully request entry of the new claims, reconsideration of this application and allowance of the pending claims to issue.

II. Rejection Under 35 U.S.C. § 112, second paragraph

A. The Office Action states that claims 1-15 and 16-21 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter with applicant regards as the invention. Specifically, the Office Action states that claims 1-15 and 16-21 are indefinite in the recitation of “fatty acid 13-hydroperoxide lyase” as the specification defines a “fatty acid 13-hydroperoxide lyase” as a lyase protein having at least one function exhibited by native 13-hydroperoxide lyase, including catalytic activity as well as antigenic activity. According to the Office Action, the definition of what applicants consider to be encompassed by the term “fatty acid 13-hydroperoxide lyase” is allegedly contrary to that which one of skill in the art would consider to be encompassed by the term. Further stated in the Office Action is that the ordinary artisan would consider a “fatty acid 13-hydroperoxide lyase” to have at the minimum enzymatic, or catalytic activity, which as defined by the specification is allegedly not essential for the described protein, only an option.

As stated above, applicants believe that one of skill in the art would understand the term “fatty acid 13-hydroperoxide lyase” to encompass enzymatic activity, as intended by applicants. However, as suggested by the Examiner, and in order to advance prosecution, claims 1-3 and 16-18 are amended herein to recite that the recombinant protein has fatty acid 13-hydroperoxide lyase activity. Thus, applicants believe this rejection has been overcome and respectfully request its withdrawal.

B. The Office Action states that claims 16-18 are indefinite in the recitation of “stringent conditions hybridization conditions” as the specification allegedly does not define what conditions constitute “stringent.” While pages 9-10 of the specification describes some conditions which are intended to be stringent, according to the Office Action, there is nothing to suggest that other conditions would not also be included within the scope of this term and in the art what is considered stringent varies widely depending on the individual situation as well as the person making the determination and thus those molecules encompassed by the set of molecules which will specifically hybridize to SEQ ID NO: 7 and do not hybridize to SEQ ID NOs: 11 or 12 changes dependent on the “stringent conditions” used. The Office Action further states that as such it is unclear how homologous to the sequence of a gene encoding SEQ ID NO: 7, a sequence must be to be included within the scope of these claims.

Claims 16-18 are amended herein to recite, in relevant part “under stringent hybridization conditions of hybridization at 5 to 20°C below the T_m in 6X SSPE followed by washing at 5 to 20°C below the T_m .” Thus, applicants have provided conditions for hybridization in the specification and as amended, claims 16-18 now recite these conditions for the hybridization reaction. Therefore, it is clear that the vectors utilized in the methods of claims 16-18 comprise a nucleic acid encoding a fatty acid 13-hydroperoxide lyase, wherein the nucleic acid specifically hybridizes with the nucleic acid of SEQ ID NO: 7 under stringent hybridization conditions of hybridization at 5 to 20°C below the T_m in 6X SSPE followed by washing at 5 to 20°C below the T_m and does not hybridize under stringent conditions to the nucleic acid set forth in SEQ ID NO: 11 or SEQ ID NO: 12. Thus, applicants have provided high stringency hybridization conditions

for selective hybridization such that the skilled artisan would be able to distinguish those nucleic acid molecules that selectively hybridize with the nucleic acid of SEQ ID NO: 7 from those nucleic acid molecules that hybridize to a nucleic acid that is not SEQ ID NO: 7, such as SEQ ID NO: 11 or SEQ ID NO: 12. Furthermore, claims 16-18 are amended herein to recite that the recombinant protein has fatty acid 13-hydroperoxide lyase activity. Thus, it is clear that only those nucleic acids which have a specific physical property (i.e. hybridize under the conditions set forth in claims 16-18) and encode a recombinant protein having a specific function (i.e. fatty acid 13-hydroperoxide lyase activity) are encompassed by the claims. Applicants believe that the scope of the claims is adequately defined. Therefore, applicants believe this rejection has been overcome and respectfully request its withdrawal.

III. Rejections Under 35 U.S.C. § 112, first paragraph

A. The Office Action states that claims 1-3 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was allegedly not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Office Action further states that claims 16-21 are rejected under 35 U.S.C. § 112, first paragraph because the specification while being enabling for those claimed methods of use of a 13-hydroperoxide lyase enzyme wherein said polypeptide comprises the amino acid sequence of SEQ ID NOs: 2, 3, 4 or 6, allegedly does not reasonably provide enablement for those claimed methods of use of a 13-hydroperoxide lyase enzyme encoded by a nucleic acid, wherein said nucleic acid specifically

hybridizes with the nucleic acid of SEQ ID NO: 7 under stringent conditions and does not hybridize under stringent conditions to the nucleic acid set forth in SEQ ID NO: 11 or SEQ ID NO: 12. The Office Action sets forth an analysis under In re Wands to support this allegation.

According to the Office Action, claims 16-21 are so broad as to encompass any method of use of a 13-hydroperoxide lyase enzyme encoded by a nucleic acid, wherein said nucleic acid specifically hybridizes with the nucleic acid of SEQ ID NO: 7 under stringent conditions and does not hybridize under stringent conditions to the nucleic acid set forth in SEQ ID NO: 11 or SEQ ID NO: 12. Also stated in the Office Action is that the specification allegedly does not support the broad scope of the claims which encompass those methods of use of any polypeptide mutant or fragment of any 13-hydroperoxide lyase encoded by a nucleic acid, wherein said nucleic acid specifically hybridizes with the nucleic acid of SEQ ID NO: 7 under stringent conditions and does not hybridize under stringent conditions to the nucleic acid set forth in SEQ ID NO: 11 or SEQ ID NO: 12 because the specification does not establish A) regions of the protein structure which may be modified without effecting 13-hydroperoxide lyase enzymatic activity; B) the general tolerance of 13-hydroperoxide lyases to modification and extent of such tolerance; C) a rational and predictable scheme for modifying any amino acid residue with an expectation of obtaining the desired biological function; and D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Applicants would like to point out that an isolated nucleic acid which specifically hybridizes with the nucleic acid of SEQ ID NO:7 under stringent conditions of hybridization and which does not hybridize at the stringent conditions to the nucleic acid set forth in SEQ ID NO:11 or SEQ ID NO:12 was found to be patentable in U.S. Patent No. 6,200,794 B1. Therefore, the currently pending methods of utilizing the nucleic acid patented in U.S. Patent No. 6,200,794 B1 should also be patentable. However, in order to advance prosecution, claims 16-18 are amended herein to specifically recite stringent hybridization conditions. Therefore, the genus of nucleic acids that can be utilized in the methods of the present invention does not encompass those methods of use of any polypeptide mutant or fragment of any 13-hydroperoxide lyase encoded by a nucleic acid, wherein said nucleic acid specifically hybridizes with the nucleic acid of SEQ ID NO: 7 under stringent conditions and does not hybridize under stringent conditions to the nucleic acid set forth in SEQ ID NO: 11 or SEQ ID NO: 12, but rather nucleic acids that 1) specifically hybridize with the nucleic acid of SEQ ID NO: 7 under stringent hybridization conditions of hybridization at 5 to 20°C below the T_m in 6X SSPE followed by washing at 5 to 20°C below the T_m and do not hybridize under stringent conditions to the nucleic acid set forth in SEQ ID NO: 11 or SEQ ID NO: 12; and 2) encode a recombinant protein that has fatty acid 13-hydroperoxide lyase activity.

It is standard in the art and well within the abilities of the skilled artisan to determine the melting temperature T_m for a hybrid formed between a reference nucleic acid (SEQ ID NO: 7) and a nucleic acid of interest in order to utilize the hybridization conditions set forth by applicants to determine whether the nucleic acid of interest hybridizes with SEQ ID NO: 7 and

does not hybridize with SEQ ID NO: 11 or SEQ ID NO: 12. Furthermore, in addition to specifically hybridizing to SEQ ID NO: 7 and not specifically hybridizing to SEQ ID NO: 11 or SEQ ID NO: 12, the nucleic acid must encode a recombinant protein with fatty acid 13-hydroperoxide lyase activity. Applicants have provided examples of recombinant, enzymatically functional fatty acid 13-hydroperoxide lyases and the assays for assessing lyase activity (pages 35-36 of the specification). Therefore, utilizing the teachings of the specification, one of skill in the art could readily identify nucleic acids that 1) specifically hybridize with the nucleic acid of SEQ ID NO: 7 under stringent hybridization conditions of hybridization at 5 to 20°C below the T_m in 6X SSPE followed by washing at 5 to 20°C below the T_m and do not hybridize under stringent conditions to the nucleic acid set forth in SEQ ID NO: 11 or SEQ ID NO: 12; and 2) encode a recombinant protein that has fatty acid 13-hydroperoxide lyase activity for use in the claimed methods. Thus, applicants believe that claims 16-18 are adequately enabled and respectfully request withdrawal of this rejection.

No additional fees are believed to be due. However, the Commissioner is hereby authorized to charge any additional fees that may be required or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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Patent Agent

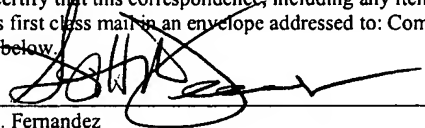
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